IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE

CHILDREN'S HEALTH DEFENSE and AMY MILLER,	)
Plaintiffs,	)
v.	)
FOOD and DRUG ADMINISTRATION, and JANET WOODCOCK, Acting Commissioner of Food and Drug Administration,	)
Defendants.	)

PLAINTIFFS' MEMORANDUM IN SUPPORT OF 1 ST AMENDED MOTION TO STAY THE FOOD and DRUG ADMINISTRATION'S BIOLOGIC LICENSE FOR THE PFIZER COMIRNATY COVID-19 VACCINE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Statutes:

Other Authority:

INTRODUCTION

This case arises out of a May 16, 2021 Citizen Petition from Children's Health Defense (CHD) to the Food and Drug Administration (FDA). CHD raised basic questions before FDA licensure of any COVID-19 vaccine. Instead of adequately addressing CHD's concerns, the FDA issued a license for the Pfizer Comirnaty vaccine on August 23, 2021, the same day it finally responded to CHD. Using an opaque licensing process that excluded even the FDA's own vaccine advisory committee as well as the public, Defendants chose to mislead the American people by licensing the largely unavailable Pfizer Comirnaty vaccine while retaining existing Pfizer Emergency Use Authorization (EUA) vaccines for the same indication on the market, in violation of federal law. The law requires FDA to make a simple choice: license a COVID-19 vaccine and revoke the existing EUA for the same vaccine and indication, or delay licensure until the product is actually available.

Important consequences flow from FDA licensure: a fully licensed vaccine has the FDA's imprimatur of "safety and efficacy," including assurances of good manufacturing and marketing practices, which make the vaccine more readily subject to mandate, while typically removing the blanket liability protection that EUA vaccines enjoy. By contrast to licensed vaccines, EUA products only "may be effective" under federal law, are exempt from certain manufacturing and marketing standards, enjoy blanket liability protection, and cannot be mandated under the plain language of federal law. Instead of an honest approach, the FDA chose a fraudulent one for one of the most important issues of the day.

The FDA told the world it had licensed the Pfizer COVID-19 vaccine, but, the vaccine it licensed – Pfizer's Comirnaty vaccine -- is largely unavailable. Many employers, including the United States military, have mandated individuals to take the "fully FDA-licensed" Comirnaty

vaccine. But the FDA "licensed" a vaccine that is not the one being mandated. The FDA is unlawfully extending the EUA for the Pfizer-BioNTech vaccine for the same 16 and up target group under the guise that the vaccine being offered is "fully FDA approved." Pfizer's Comirnaty mRNA vaccine received full FDA approval. But in a maze of fine print, the FDA admits the supply of the Comirnaty is insufficient.

Specifically, footnote 9 of the FDA approval letter states: "there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA." Concurrently, the FDA granted an updated EUA to the widely distributed and "interchangeable" Pfizer-BioNTech mRNA vaccine, noting there was a "significant amount" available. Since the FDA violated federal law when it again granted the EUA for the Pfizer-BioNTech product for those aged 16 and up for first and second doses, this Court should stay FDA's biologic license for the Pfizer Comirnaty vaccine until Pfizer can make sufficient doses available of the licensed product. The FDA's bait-and-switch operation is illegal, injurious, and should be stopped.

FACTS

Typically, vaccine development includes six stages: (1) exploratory; (2) preclinical (animal testing); (3) clinical (human trials); (4) regulatory review and approval; (5) manufacturing; and (6) quality control.[1] Suffice it to say, FDA approval for a typical vaccine is often lengthy and complex. Generally, it takes five to ten years, at minimum, to develop a vaccine, from inception to administration to the public.[2] Several years are dedicated to

[1] *See*, CDC, Vaccine Testing and the Approval Process (May 1, 2014), available at https://bit.ly/3rGkG2s (last visited August 26, 2021).
[2] *Vaccine Research and Development*, Johns Hopkins University, available at https://coronavirus.jhu.edu/vaccines/timeline.

performing adequate tests and clinical trials to ensure the safety and efficacy of a vaccine prior to FDA licensure.

In contrast to this six-step approval process, Congress vested the Health and Human Services Secretary ("Secretary") with the power to "authorize the introduction into interstate commerce, during the effective period of a declaration of emergency…a drug, device, or biological product intended for use in an actual or potential emergency. . ." 21 U.S.C. § 360bbb3(a)(1) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA"). Under this statute, the FDA may grant emergency use authorization for a vaccine not yet approved or licensed for use under the typical regulatory regime. When there are no FDA-licensed, available alternatives, and other important criteria are met, FDA can make vaccines available under an emergency access mechanism called "Emergency Use Authorization" (EUA).[3]

EUAs allow the FDA to make a product available to the public quickly based on the best available data, without waiting for all the evidence needed for licensure.[4] The important distinction is between "authorization" for an EUA vaccine and "licensure" for an "approved vaccine." While in other legal contexts, "authorized," "approved," and "licensed" may be used synonymously, that is not the case here. There is a world of difference between what the FDA "authorizes," which "may be effective," and what the FDA "licenses," where the FDA has vetted the manufacturers' clinical trial data and has determined that the vaccine IS "safe and effective."[5]

EUAs are used in times of emergencies to "facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current

[3] *See generally,* FDA, Emergency Use Authorization for Vaccines Explained (Nov. 20, 2020), available at bit.ly/3x8wImn (last visited August 26, 2021).
[4] *See,* FDA, *Emergency Use Authorization for Vaccines Explained* (Nov. 20, 2020), available at bit.ly/3x8wImn (last visited August 29, 2021).
[5] 21 U.S.C. § 360bbb-3.

COVID-19 pandemic."[6] Thus, the goal of the EUA process is to cut the red tape, providing a stopgap measure until a product, drug, vaccine, or device receives full FDA licensure.

Criteria for Emergency Use Authorization

First, when issuing an EUA under Section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act, the Secretary ("Secretary") of Health and Human Services (HHS) must first declare that circumstances exist to justify the emergency use of experimental products.[7] On or about February 4, 2020, the Secretary determined COVID-19 presented a public health emergency.[8] Furthermore, on or about March 27, 2020, the Secretary determined that circumstances existed to justify the authorization of emergency use of drugs and biological products.[9]

Second, after the Secretary declares that circumstances exist to justify the emergency use of experimental products, the Secretary must then make several additional determinations before any product, device, vaccine or drug can be authorized for emergency use.

21 U.S.C. § 360bbb-3(c)(1)-(3) lays out three additional criteria required to grant emergency use authorization for a product. At issue here is the third criterion, which requires the Secretary to conclude "that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition..."[10]

---

[6] FDA, Emergency Use Authorization for Vaccines Explained (Nov. 20, 2020), available at bit.ly/3x8wImn (last visited August 26, 2021).
[7] 21 U.S.C. § 360bbb-3; 85 FR 18250; See also, CDC, Fact Sheet for Patients, Centers for Disease Control and Prevention, (July 21, 2021), available at https://www.fda.gov/media/144414/download (last visited Sept. 4, 2021).
[8] 85 FR 18250, available at https://www.govinfo.gov/content/pkg/FR-2020-04-01/pdf/2020-06905.pdf (last visited Sept. 4, 2021).
[9] *Id.*
[10] 21 U.S.C. § 360bbb-3(c)(3) (emphasis added).

The Defendants' Harmful Bait-and-Switch

The definition of an unlawful bait-and-switch is an insincere offer to sell one item to induce a buyer to purchase another.[11] That is precisely what the FDA has done, although admittedly in a novel context.

The Pfizer-BioNTech COVID-19 vaccine was first authorized for emergency use by the FDA on December 11, 2020, pursuant to 21 U.S.C. § 360bbb-3, for individuals 16 years of age and older, and later for individuals 12-15 years of age, and later still as a third dose for highly immunocompromised individuals.

The FDA subsequently reauthorized Pfizer-BioNTech COVID-19 vaccine for emergency use on August 23, 2021.[12] The letter of authorization from August 23, 2021 reads in part:[13]

> "[F]DA is reissuing the August 12, 2021 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses, and to authorize use of Comirnaty (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved BLA."

In a section outlining the criteria of re-issuance from the August 23, 2021 letter, the Secretary contorts 21 U.S.C. § 360bbb-3(c)(3) to mean something it does not. Buried in the fine print of a footnote, the Secretary writes: "although Comirnaty (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA."[14]

The same day the FDA reauthorized the EUA for the Pfizer-BioNTech COVID-19

---

[11] David Adam Friedman, *Explaining "Bait-and-Switch" Regulation*, 4 Wm. & Mary Bus. L. Rev. 575 (2013), https://scholarship.law.wm.edu/wmblr/vol4/iss2/6.
[12] FDA, Pfizer-BioNTech COVID-19 Vaccine EUA LOA Reissued, (Aug. 23, 2021) available at https://www.fda.gov/media/150386/download last visited on (Aug. 28, 2021).
[13] *Id.*
[14] *See*, Ftn. 9 (emphasis added).

vaccine, the agency also granted the biologic license application (BLA) for the Pfizer Comirnaty vaccine to prevent COVID-19 in individuals 16 years of age and older for first and second doses.[15]

The fact sheet provided by the FDA on August 23, 2021 for healthcare providers administering the EUA-Pfizer-BioNTech vaccine reads:[16]

> The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the EUA authorized Pfizer-BioNTech COVID-19 Vaccine have the *same formulation and can be used interchangeably to provide the COVID-19 vaccination series*. (emphasis added).

But, in the fine print of footnote 1 on the fact sheet for healthcare providers, the FDA admits that the two vaccines are "legally distinct" from one another.[17] Similarly, the FDA acknowledges the EUA Pfizer-BioNTech vaccine is "[l]egally distinct" from the FDA-approved Comirnaty vaccine in the agency's approval letter to Pfizer dated August 23, 2021.[18]

In sum, on the same day the FDA granted full approval and licensure to the Pfizer Comirnaty vaccine, it also reissued an EUA for the Pfizer-BioNTech COVID-19 vaccine for the same indication, i.e. for prevention of COVID-19 in individuals 16 and up. In doing so, the FDA violated federal law, 21 U.S.C. § 360bbb-3(c)(3), by authorizing continuing use of the Pfizer-BioNTech COVID-19 vaccine when an identical vaccine, Pfizer's Comirnaty vaccine, was fully licensed. FDA is mangling federal law to suggest that insufficient supply to distribute to the population in its entirety is the basis for concurrent licensure and EUA – the FDA has made a

---

[15] FDA, FDA Approval Letter to Pfizer, (August 23, 2021) available at https://www.fda.gov/media/150386/download (last visited Sept. 4, 2021).
[16] FDA, *Fact Sheet for Healthcare Provider Administering Vaccine (Vaccination Providers)*, (Aug. 23, 2021) available at https://www.fda.gov/media/144413/download (last visited Aug. 26, 2021).
[17] Available at https://www.fda.gov/media/144413/download
[18] FDA, *Pfizer-BioNTech COVID-19 Vaccine EUA LOA Reissued*, (Aug. 23, 2021) available at https://www.fda.gov/media/150386/download (last visited on Aug. 28, 2021).

bridge too far.

Either Pfizer's vaccine for people 16 and up is licensed or it's EUA – it can't be both simultaneously under federal law. Either it's available or it's not available – it can't be "approved" and "not approved" and "available" and "not available" all at the same time -- which is what the FDA has green-lighted, enabling Pfizer's bait-and-switch that the vaccines are all "interchangeable" and thus "approved and licensed."

Liability Shield

All EUA COVID-19 vaccines enjoy an extraordinary liability shield under the 2005 Public Readiness and Emergency Preparedness Act ("PREP Act"). Vaccine manufacturers, distributors, providers, and government planners are immune from any realistic liability. The only way an injured party can sue is if he or she can prove willful misconduct by clear and convincing evidence after having exhausted all administrative remedies, from which there would otherwise be no right of judicial appeal.[19]

No such lawsuit for willful misconduct against an EUA product manufacturer or purveyor has ever succeeded. Courts characterize PREP Act immunity as "sweeping."[20] It applies to all types of legal claims under state and federal law. *Id*. In short, the COVID-19 EUA vaccines enjoy an almost unimaginable liability shield under the PREP Act.

On March 10, 2020, the Secretary invoked the PREP Act and determined that COVID-19 constitutes a public health emergency.[21] As a result, Pfizer, Moderna, and Johnson & Johnson,

---

[19] 42 U.S.C.S. § 247d-6d.

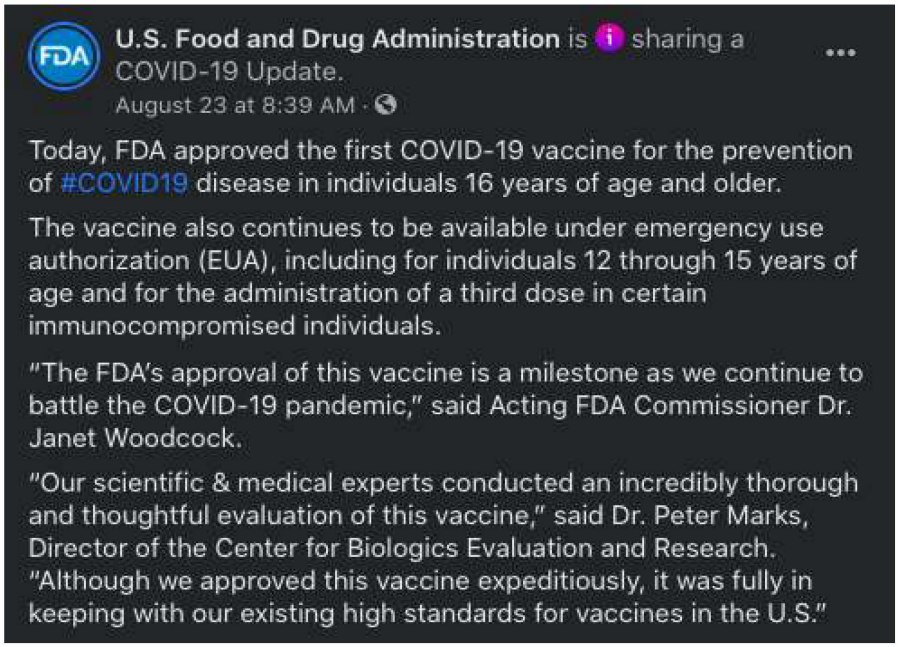
[20] See, Congressional Research Service, *The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures*, (March 19, 2021) available at https://crsreports.congress.gov/product/pdf/LSB/LSB10443#:~:text=To%20encourage%20the%20expeditious%20development,to%20the%20administration%20of%20medical (last visited Aug. 26, 2021).

[21] *The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures.*

the leading COVID-19 vaccine manufacturers in the United States, enjoy blanket liability protection from liability for severe adverse effects and harms, including permanent disabilities and death, resulting from COVID-19 EUA vaccines.

Defendants willfully failed to follow the statutory scheme outlined in 21 U.S.C. § 360bbb-3(c) when the FDA reauthorized the Pfizer-BioNTech COVID-19 vaccine for emergency use while misleading the public into believing that a fully licensed vaccine, the Comirnaty vaccine, was widely available in the U.S. The FDA Acting Commissioner Woodcock, the FDA and other U.S. government officials willfully misled the American public, including members of the military, by conflating the two vaccines and falsely claiming that the Pfizer COVID-19 vaccine currently available, i.e. the Pfizer-BioNTech vaccine, is fully FDA-approved (see examples below).[22]

[22] U.S. Food and Drug Administration, (@FDA) FDA Approves First COVID Vaccine, (Aug. 23, 2021) available at https://www.facebook.com/FDA/posts/10159678210002299 (last visited Sept. 5, 2021).



Note the FDA's misleading Facebook post from August 23, 2021, which fails to state the Pfizer EUA vaccine is available for those 16 and up, the same indication as the Comirnaty vaccine. The post just describes the different, appropriate EUA indications -- for individuals 12 through 15 years and for booster shots. But the FDA deceptively neglected to share that the Comirnaty vaccine is for precisely the same indication as for the Pfizer-BioNTech vaccine, i.e. administration in those 16 and up. This Facebook post exemplifies FDA's scheme: use the approved Comirnaty vaccine to market the Pfizer EUA vaccine.

COVID-19 Vaccination Mandates Following FDA "Licensure"

After the misleading advertisements and press statements by Defendants on and after August 23, 2021, the military and others have mandated vaccination with the "FDA approved vaccine." As a result, vast numbers of Americans, including hundreds of thousands of military service members, are currently being misled into receiving the Pfizer-BioNTech COVID-19 EUA vaccine while believing they are receiving the fully licensed, FDA-approved Comirnaty vaccine. If injured by the Pfizer-BioNTech COVID-19 vaccines, individuals are unlikely to ever

be made whole financially, let alone physically. Without a stay, Plaintiffs and those similarly situated will be harmed by the FDA's unlawful bait-and-switch.

LEGAL STANDARD

When deciding whether to grant a stay, courts typically consider four factors, the same factors used to evaluate a motion for a preliminary injunction:[23] Courts consider whether Plaintiffs have shown: (1) the likelihood of success on the merits, (2) the likelihood of irreparable harm to them in the absence of a stay, (3) that the balance of equities weighs in plaintiffs' favor, and (4) that a stay is in the public interest. While authority is split regarding how to weigh certain factors or whether to use a sliding scale, in either case the "third and fourth factors, harm to the opposing party and the public interest, merge when the Government is the opposing party."[24]

The Administrative Procedures Act's (APA) stay provision allows courts to grant a stay on the proceedings in cases properly arising out of the APA. 5 U.S.C. § 705 provides that:

> When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings. (emphasis added).

[23] *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 25 (2008); *See also*, Fed. R. Civ. P. 65.
[24] *Nken v. Holder*, 556 U.S. 410, 420 (2009); See, e.g., *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 51 (2008) (Ginsburg, J., dissenting); Eric J. Murdock & Andrew J. Turner, *How "Extraordinary" Is Injunctive Relief in Environmental Litigation? A Practitioner's Perspective*, 42 ENVTL. L. REP. NEWS & ANALYSIS 10464 (2012).

The APA defines agency action as a "rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act."[25]

In *Sampson v. Murray*, 415 U.S. 61 (1974), the Supreme Court relied on the APA's legislative history to observe that § 705 was intended to codify the existing power of federal courts to issue a stay.[26] While both stays and preliminary injunctions are temporary remedies, stays are different from preliminary injunctions in one important way: preliminary injunctions act on the person while stays act on the proceeding.[27]

Under APA § 705, the Court is obliged, in the interest of justice and to prevent irreparable injury, to stay the biologic license that the FDA unlawfully granted to Pfizer's Comirnaty vaccine while it simultaneously authorized Pfizer to retain an EUA for the identical product with the same indication.

ARGUMENT AND AUTHORITIES

I. Petition to Review FDA's Grant of a Biologic License to Pfizer's Comirnaty Vaccine is Likely to Succeed on the Merits

"The first factor, a strong showing of a likelihood of success on the merits, requires more than a mere possibility that relief will be granted."[28] In this case, there is a strong likelihood that the Court will find that FDA's grant of a biologic license to Pfizer's COVID-19 Comirnaty vaccine is arbitrary and capricious agency action and should be invalidated.

A. The FDA's Licensure of Pfizer's Comirnaty Vaccine is Arbitrary and Capricious under APA 5 U.S.C. § 706(2)(A)

[25] 5 U.S.C. § 551(13).
[26] *Id*. at 68 n.15 (citing S. REP. NO. 752, at 230 (1945)) (citing S. REP. NO. 752, at 230 (1945)).
[27] *Nken v. Holder*, 556 U.S. 418, 432–33. (2009).
[28] *Id*. at 420.

The Administrative Procedures Act (APA) protects the public from arbitrary and capricious executive branch action by imposing the rule of reason and the rule of law through judicial oversight. An agency is "required to engage in reasoned decision making."[29] This requires that the agency "articulate a satisfactory explanation for its action."[30] This process requires Defendants to articulate clear rationales for decisions, especially when their actions are bound to lead to medical mandates with severe consequences for millions of people.[31]

Defendants' action to license Pfizer's Comirnaty vaccine has misled the public to believe that the vaccine being mandated is fully FDA-approved when in fact it is actually Pfizer's EUA product. The FDA unlawfully, arbitrarily and capriciously allowed Pfizer to represent its Comirnaty vaccine as licensed and available while selling off its inventory of EUA vaccines that are legally distinct from the Comirnaty vaccine and are afforded blanket liability protection. Pfizer represents that its Comirnaty vaccine also has blanket liability protection under the PREP Act.

Furthermore, *Rumsfeld #1* stands for the proposition that where a controlling statute prohibits administration of experimental investigational new drugs, or drugs unapproved for their intended use, without the informed consent of the person to whom the drug is to be administered, any program or mandate inconsistent with the controlling statute is illegal.[32] *Rumsfeld #1* granted a preliminary injunction against the Department of Defense after it instructed military service personnel and civilian contractors to submit to anthrax vaccinations with "an investigational drug and a drug being used for an unapproved purpose" without their informed consent.[33]

---

[29] *Michigan v. EPA*, 576 U.S. 743, 750 (2015).
[30] *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co*., 463 U.S. 29, 43 (1983).
[31] *Burlington Truck Lines v. United States*, 371 U.S. 156, 158 (1962).
[32] *Doe # 1 v. Rumsfeld*, 297 F. Supp. 2d 119, 125 (D.D.C. 2003) (*Rumsfeld #1)*
[33] *Id.* at 135.

Later upholding its injunction, the Court stated "[u]nless and until FDA properly classifies [the anthrax] vaccine as a safe and effective drug for its intended use, an injunction shall remain in effect prohibiting defendants' use of [it] on the basis that the vaccine is either a drug unapproved for its intended use or an investigational new drug within the meaning of 10 U.S.C. § 1107. Accordingly, the involuntary anthrax program…is rendered illegal absent informed consent or a Presidential waiver…."[34]

Rumsfeld #1 was decided on statutory grounds, 10 U.S.C. § 1107, which "prohibits the administration of investigational new drugs, or drugs unapproved for their intended use, to service members without their informed consent[,]" absent a Presidential waiver.[35] There, like here, "the central question [was] whether [the anthrax vaccine] [was] being used as an investigational new drug or as a drug unapproved for its intended use."[36]

Applying *Rumsfeld #1* to the Department of Defense's COVID vaccine mandate, the three of the COVID-19 vaccines service members may choose from are experimental drugs, still in the clinical trial phase, which are unapproved products, and are not licensed by FDA for any indication. The fourth vaccine, Comirnaty, while fully approved is not available in sufficient stock.[37]

II. Plaintiffs Will Suffer Irreparable Harm Absent a Stay

The FDA's grant of a biologic license for Pfizer's Comirnaty vaccine, while reissuing the EUA for the Pfizer-BioNTech vaccine, created the false impression that the vaccines being

[34] *Doe v. Rumsfeld*, 341 F.Supp.2d 1, 19 (D.D.C. 2004) (*Rumsfeld #2*).
[35] *Rumsfeld #1,* at 125.
[36] *Id*. at 131.
[37] Letter of EUA Authorization (Reissued), https://www.fda.gov/media/150386/download, p. 5, n. 9.

routinely administered at present are fully FDA-licensed. While the FDA license approved [Pfizer] to manufacture COVID-19 vaccine[38] for distribution to individuals 16 and older, the FDA simultaneously renewed the EUA for the Pfizer-BioNTech COVID-19 vaccine for its previously authorized indication and use, in addition to new indications. The renewed Letter of Authorization for the EUA stated that "although Comirnaty (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population at the time of reissuance of this EUA."[39] Therefore, the vast majority of Pfizer COVID-19 vaccines on the market are unlicensed and actually only marketable under EUA. The FDA acknowledges as much, writing that there is not sufficient approved vaccine available for distribution for people aged 16 and older.[40]

The plain text of 21 U.S.C. § 360bbb-3(c)(3) is clear: the Secretary must conclude "that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition...." The law states three criteria: (1) adequate, (2) approved, and (3) available for the alternative that must exist to enable an EUA. These are concurrent conditions, not disjunctive conditions. These are "and" factors, not "or" factors. The licensed product must be adequate, approved, AND available as the alternative to the EUA. If the licensed product does not constitute that alternative – if it is not adequate, approved, and available, then it should not preempt the EUA product. The EUA should continue until such time as the licensed product is adequate, approved, and available. The distinction between a licensed product and an EUA product should be a bright line – not the blur that the FDA has made of it.

[38] BLA Approval Letter, https://www.fda.gov/media/151710/download, p. 1.
[39] Letter of EUA Authorization (Reissued), https://www.fda.gov/media/150386/download, p. 5.
[40] *Id* at p. 5, n. 9.

However, following the FDA's biologic license for Comirnaty, COVID-19 vaccine mandates have been implemented at an alarming rate. For example, one day after the FDA granted the biologic license for Pfizer's COVID-19 Comirnaty vaccine on August 23, 2021, the Department of Defense announced that all US military members must be vaccinated for COVID-19: a direct result of the false representation of the current marketable Pfizer vaccine as FDA-approved.[41] Recently, President Joe Biden also decreed that vast numbers of the federal workforce and millions of private employees must be vaccinated or face serious consequences.[42]

The FDA's cynical wordplay regarding a COVID vaccine license set off a firestorm, misleading institutions to coerce unlicensed, experimental mRNA vaccines on service members and employees. The FDA has allowed Pfizer and federal agencies (including the Department of Defense) to falsely boast and mislead about the "safety and efficacy," of the EUA-Pfizer vaccine.

A. Without a stay, scores of soldiers, sailors, airmen, and marines will face irreparable and immediate harm as a result of COVID-19 vaccine mandates

In mandating COVID-19 vaccines for all enlisted service members, the military has relied on FDA's assurance of licensure. On or about August 24, 2021, Secretary of Defense Llyod Austin issued guidance for mandatory COVID-19 vaccination and "direct[ed] the Secretaries of the Military Departments to immediately begin full vaccination of all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the

[41] *Memorandum for Senior Pentagon Leadership Commanders of the Combatant Commands Defense Agency and DOD Field Activity Directors,* Secretary of Defense (August 24, 2021) available at https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF.

[42] Adam Freedman, *Biden's Vaccine Mandate is Unconstitutional*, City Journal (Sept. 15, 2021) available at https://www.city-journal.org/biden-vaccine-mandate-unconstitutional (last visited Sept. 16, 2021).

National Guard, who are not fully vaccinated against COVID-19."[43]

The memorandum then states that "mandatory vaccination against COVID-19 *will only use* COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA)."[44] Secretaries of the Military Departments were ordered to implement "ambitious timelines" for enforcement.[45]

Following the Defense Secretary's order, the United States Army recently outlined a plan to mandate COVID-19 vaccinations on troops.[46] In ordering the vaccine, the Army publicly proclaimed that any soldier who refuses to be vaccinated and fails to qualify for an Army-approved exemption will face harsh reprimands.[47] In an apparent effort to scare soldiers into taking the vaccine, the Army's press release asserts such reprimands "can be career ending."[48]

The Army further warns that officers and noncommissioned officers in positions of leadership who refuse to be vaccinated will face suspension and relief of duties.[49] Moreover, those who have been selected for promotion - "some of the most coveted assignments in the Army" - will be removed from promotional lists and stripped of their opportunity to advance up the chain of command.[50] Yet, under the Department of Defense's own guidance and federal

---

[43] https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FORMANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OFDEFENSE-SERVICE-MEMBERS.PDF

[44] *Id*.

[45] *Id*.

[46] U.S. Army Public Affairs, *Army announces implementation of mandatory vaccines for Soldiers*, U.S. Army (Sept. 14, 2021) available at https://www.army.mil/article/250277/army_announces_implementation_of_mandatory_vaccines_for_soldiers (last visited Sept. 15, 2021).

[47] *Id*.

[48] *Id*.

[49] *Id*.

[50] *Id*.

precedent from *Doe v. Rumsfeld*, 297 F.Supp.2d 119 (2003), it is clear the military cannot mandate COVID-19 vaccines while the available product is unlicensed. But the military services are actively forcing service members to receive EUA vaccines in lieu of licensed one. This is aided by FDA's bait-and-switch, which has allowed the military to mandate the vaccines under the false flag that the EUA-Pfizer vaccine is a fully approved and licensed FDA product.

If Plaintiffs were to receive a vaccine now, they would almost certainly receive an EUA product, to which they have a legal right to refuse. Under federal law, individuals to whom an EUA product is administered must be informed "of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). Federal precedent establishes that military service members have an absolute right to refuse EUA vaccines without punishment.[51] Through the actions of the FDA approval of Comirnaty the military has mandated the vaccine without the acknowledgment that the actual vaccine service members are receiving is one that they have a right to refuse and is not fully approved. Thus, the punishments being meted out to the service members deny them their absolute right to refuse EUA vaccines.

Plaintiff Children's Health Defense brings this suit on behalf of its members, including numerous service members (see declarations attached as exhibits 3-16), who will suffer irreparable and immediate harm if they are subject to vaccine mandates resulting from deceitful, factual misrepresentations by the FDA.

The unwanted effects of an experimental mRNA COVID-19 vaccine are irreversible in some individuals; there is significant potential for harm if individuals are forced to receive a

[51] *Doe #1 v. Rumsfeld*, 297 F.Supp.2d 119 (2003) ("...the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." *Id*. at 135)

vaccine with virtually no liability when they mistakenly believe that they are receiving an FDA-licensed product for which there is some legal recourse. Even though the available vaccines are overwhelmingly EUA, individuals (including service members) are being told that they will suffer significant harm to their careers, education, property, and civil liberties if they refuse. Military members have been threatened with severe consequences for refusal. *See*, Declaration of Pam Long, Exh. 01.

The FDA's illegal "approval" of the Pfizer COVID-19 vaccine has helped the United States Department of Defense justify harsh COVID-19 vaccine mandates that have resulted in an abundance of coercion. U.S. military members have been threatened with harsh consequences for refusing to receive the EUA-Pfizer vaccine. A bevy of honorable service members have uncovered the FDA's deceitful scheme, which risks causing irreparable harm by duping unsuspecting military members into believing they are receiving a vaccine with certain legal protections and assurances when in fact they have no real legal protection at all. Even worse, as the military declarations firmly establish, the FDA's abject lawlessness paved the way for the U.S. military to treat our heroes in uniform as guinea pigs for experimental drugs. It imposed career-ending punishment on any service member who dared to ask: "Why shouldn't the FDA be forced to follow the law?"

"The Court is persuaded that the right to bodily integrity and the importance of complying with legal requirements, even in the face of requirements that may potentially be inconvenient or burdensome, are among the highest public policy concerns one could articulate. *Doe # 1 v. Rumsfeld*, 297 F. Supp. 2d 119, 13 (2003). "…. the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." *Id.* at 135. The

court ruled that "requiring a person to submit to an inoculation without informed consent or the presidential waiver is an irreparable harm for which there is no monetary relief." *Id.* at 135 (Op).

Even though the Department of Defense knows it is against the law to force experimental vaccines on our men and women in uniform, it mercilessly tricks, discriminates and coerces them into participating in an unlawful experiment. Service member's careers should not be ended simply because they exercise their rights under federal law. But, they risk more than dishonorable discharge, demotion, an end to their VA benefits, pensions, and medical insurance. As many are sole breadwinners, their families too risk irreparable harm simply because the service member refuses an experimental vaccine.

We include declarations from 14 military service members, who are also members of Children's Health Defense. We received over 100 declarations in two days and would be happy to provide them to the court, if helpful. The declarations attached are illustrative. They are from brave men and women of different branches of the service who put their careers at risk to submit them. The declarations detail with striking clarity the service member's legitimate, well-founded, and documented concerns regarding the safety and efficacy of unlicensed vaccines. Those who have sought religious, medical, and serological exemptions report that their commanders have already told them all exemptions will be denied.

It is striking that more than half of the declarations demonstrate that the service member has already acquired natural immunity to COVID. Army Regulation 40-562 ("AR 40-562") is the all-service publication that governs the administration of "Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases." The regulation provides documented survivors of an illness a presumptive exemption from vaccination for that illness. The regulation includes the

following as basis for exemptions: "Evidence of immunity based on serologic tests, documented infection, or similar circumstances." AR 40-562 ¶2-6a. (1)(b).

In August of this year, the FDA had a simple choice: it could either follow federal law or not. Sadly, the agency chose the latter, disregarding the will of Congress and then misleading the American people about what it had done. Plaintiffs have shown the FDA's lawlessness has caused and will continue to cause irreparable harm. This scheme to coerce service members to receive EUA vaccines would not exist without the FDA's unlawful actions, which created mass confusion, disorder, and deception, regarding the differences between the two Pfizer vaccines.

III. The Issuance of a Stay Will Not Substantially Injure Others and Furthers the Public Interest

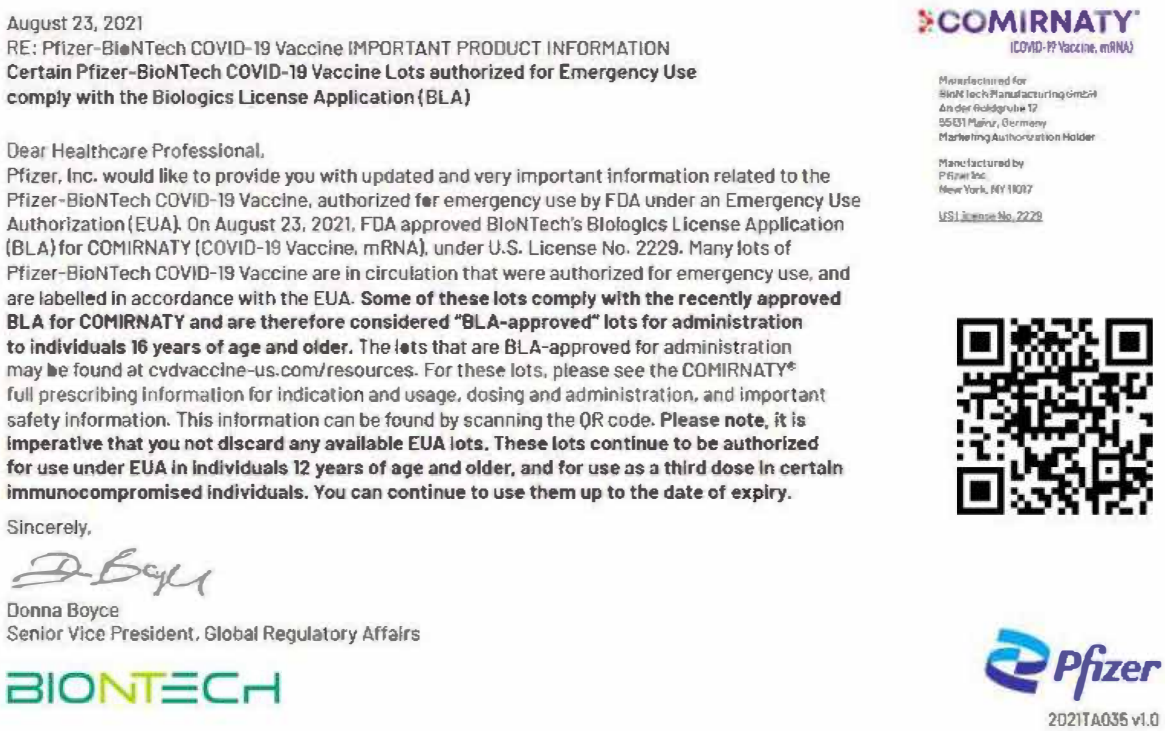
"The third and fourth factors, harm to the opposing party and the public interest, merge when the Government is the opposing party."[52] Here, the FDA, acting in its capacity as a federal agency within the Department of Health and Human Services, has executed government action. Therefore, courts merge consideration of agency harm into the public interest analysis.

Generally, when looking at the effect an action may have on the public interest, courts consider not only the law but also ethics. According to the American Medical Association, under the Code of Medical Ethics, it is a patient's right to be able to give informed consent to her physician when considering medical care or treatment.[53] Informed consent fosters trust and support in the doctor-patient relationship. It is in the public interest that those seeking vaccines receive accurate, truthful, complete information, and that they give informed consent or informed refusal. To be able to give informed consent, the patient must be able to understand: (1) the

[52] *Nken v. Holder* at 420 (2009).
[53] *Code of Medical Ethics Opinion 2.1.1, ama-assn.org (September 5, 2021)* https://www.amaassn.org/delivering-care/ethics/informed-consent

relevant medical information and the implications of treatment alternatives for an independent, voluntary decision; (2) the burdens, risks, and expected benefits of all options, including alternative treatments; and (3) the documentation the healthcare workers provide. The first requirement is most relevant here.

The FDA's action of misleading not only Plaintiffs but the entire American public, has created the illusion that a licensed COVID-19 vaccine exists that they can receive. The reality is that the FDA is purposefully conflating the two Pfizer vaccines in the examples shown above.[54] The FDA has permitted Pfizer to claim to the world that some of its EUA vaccines are considered "BLA-approved." *See*, below and Exh. 02.



August 23, 2021
RE: Pfizer-BioNTech COVID-19 Vaccine IMPORTANT PRODUCT INFORMATION
Certain Pfizer-BioNTech COVID-19 Vaccine Lots authorized for Emergency Use comply with the Biologics License Application (BLA)

Dear Healthcare Professional,
Pfizer, Inc. would like to provide you with updated and very important information related to the Pfizer-BioNTech COVID-19 Vaccine, authorized for emergency use by FDA under an Emergency Use Authorization (EUA). On August 23, 2021, FDA approved BioNTech's Biologics License Application (BLA) for COMIRNATY (COVID-19 Vaccine, mRNA), under U.S. License No. 2229. Many lots of Pfizer-BioNTech COVID-19 Vaccine are in circulation that were authorized for emergency use, and are labelled in accordance with the EUA. **Some of these lots comply with the recently approved BLA for COMIRNATY and are therefore considered "BLA-approved" lots for administration to individuals 16 years of age and older.** The lots that are BLA-approved for administration may be found at cvdvaccine-us.com/resources. For these lots, please see the COMIRNATY® full prescribing information for indication and usage, dosing and administration, and important safety information. This information can be found by scanning the QR code. **Please note, it is imperative that you not discard any available EUA lots. These lots continue to be authorized for use under EUA in individuals 12 years of age and older, and for use as a third dose in certain immunocompromised individuals. You can continue to use them up to the date of expiry.**

Sincerely,

Donna Boyce
Senior Vice President, Global Regulatory Affairs

BIONTECH

COMIRNATY
(COVID-19 Vaccine, mRNA)

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
Pfizer Inc.
New York, NY 10017

US License No. 2229

Pfizer

2021TA035 v1.0

[54] U.S. Food and Drug Administration, (@FDA) *FDA Approves First COVID Vaccine*, (Aug. 23, 2021) available at https://www.facebook.com/FDA/posts/10159678210002299 (last visited Sept. 5, 2021).

Federal law is clear: vaccines are either permitted under the EUA or they are fully licensed. The FDA is fully aware of this important distinction, but it has unlawfully permitted Pfizer to completely blur this line and to pretend that EUA vaccines are fully licensed. Millions of Americans, including our heroes in uniform, now face draconian vaccine mandates that threaten their property and liberty. Deceiving people about a product that carries risks that include injury and death is unconscionable and illegal. Undoubtedly, such deception erodes public confidence in public health generally.

The public is served by protecting the sacred right of informed consent, especially as it pertains to emergency use products. Moreover, the law is absolute in its requirement that EUA products only exist when "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition..." 21 U.S.C. § 360bbb-3(c)(3) (emphasis added). By granting a stay on the FDA's biologic license to Pfizer for the Comirnaty vaccine until it is actually available, this Court will end the FDA's bait-and-switch and require that it follow the law. Such a stay would mean that Defendants have to be honest with the American public. Particularly in the midst of a pandemic, the American people, including our service members in harm's way, deserve no less from their government.

CONCLUSION

For all these reasons, this Court should grant Plaintiffs' Motion for Stay and direct the FDA to comply with federal law and suspend its license for Pfizer's Comirnaty vaccine while any Emergency Use Authorization still exists for the same product for the same indication, pending judicial review of Plaintiffs' complaint.

Dated: September 17, 2021

Respectfully submitted,

__/s/ Derek Jordan_____

Derek Jordan, Esq.
Tennessee Bar No. 34299
Email: derekjordan@barneslawllp.com
Robert E. Barnes, Esq.
Subject to admission Pro Hac Vice
Email: robertbarnes@barneslawllp.com
BARNES LAW
700 South Flower Street, Suite 1000
Los Angeles, California 90017
Telephone: (310) 510-6211

Ray L. Flores II
Subject to admission Pro Hac Vice
Email: rayfloreslaw@gmail.com
11622 El Camino Real Suite 100
San Diego, CA 92130
Telephone: (858) 367-0397

Robert F. Kennedy, Jr., Esq.
Mary S. Holland, Esq.
Subject to admission Pro Hac Vice
Email: mary.holland@childrenshealthdefense.org
Children's Health Defense
1227 N. Peachtree Pkwy, Suite 202
Peachtree City, GA 30269

Counsel for Plaintiffs CHILDREN'S HEALTH DEFENSE and AMY MILLER